UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

FREEDOM COALITION OF DOCTORS FOR CHOICE, Plaintiff, v. CENTERS FOR DISEASE CONTROL AND PREVENTION and DEPARTMENT OF HEALTH & HUMAN SERVICES, Defendants.	Civil Action No. 2:23-cv-00102-Z

PLAINTIFF'S REPLY TO DEFENDANTS' RESPONSE TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT AND RESPONSE TO DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

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Plaintiff Freedom Coalition of Doctors for Choice ("**Freedom Coalition**" or "**Plaintiff**") files this reply in support of its Motion for Summary Judgment, (Dkt. 8), and in opposition to defendants Centers for Disease Control and Prevention ("**CDC**") and the U.S. Department of Health and Human Services' ("**HHS**") (collectively, "**Defendants**") Cross-Motion for Summary Judgment, (Dkt. 27).

ARGUMENT

"Congress has long recognized that 'information is often useful only if it is timely' and that, therefore 'excessive delay by the agency in its response is often tantamount to denial.'" *Open Soc'y Just. Initiative v. CIA*, 399 F. Supp. 3d 161, 165 (S.D.N.Y. 2019) (quoting H.R. REP. NO. 93-876, at 6271 (1974)). Here, Defendants seek to withhold the most critical and informative dataset available for assessing the safety and efficacy of the existing COVID-19 vaccines—data that will directly shed light on and contribute to the public's understanding of the government's activities during COVID-19 and its vaccine campaign. As noted, Plaintiff takes no position on the data other than it should be made available to the public and scientific community as soon as possible, which it intends to do promptly if and when the data is released via its website, www.drsforchoice.org. The Court should grant Plaintiff's Motion for Summary Judgment and deny Defendants' Cross-Motion for Summary Judgment ("**Defendants' Motion**").

While Defendants spill significant ink on irrelevant issues, this case turns squarely on whether or not Defendants have an obligation to redact and release data from a program: (1) funded by taxpayers; (2) that was designed to monitor a vaccine taxpayers funded and paid to purchase; and (3) that paved the way for the vaccine to be mandated on the public under threat of losing jobs, being denied schooling, being discharged from the military, or otherwise being excluded from civil society due, in large part, to the federal government. Tellingly, the protocol of the program at

issue—v-safe—was recently modified to explicitly call for the deidentification and release of individual level data, which is precisely what Plaintiff is requesting. But Defendants have made plain that they have no intention of actually making the data public (unless required to do so by this Court). While the CDC may consider its FOIA office overburdened, that hardly means Defendants are excused from their statutory obligations to review and produce data.

Critically, many of the issues CDC now complains of in releasing the data were entirely the result of its own choices. The Court should not reward this behavior by allowing CDC to hide behind its own unforced errors at the expense of the American taxpayers' ability to access vital information about the federal government's actions during COVID-19—particularly where CDC has already demonstrated it has the ability to do a complex review of these free-text entries at a rate of 837,000 entries per month via its existing MedDRA contract. Defendants should therefore be required to produce this crucial data, on a rolling basis, with production being complete within at least 9.3 months of the Court's order, if not sooner.

I. PLAINTIFF DOES NOT CHALLENGE THE ADEQUACY OF CDC'S SEARCH.

As Defendants point out, the v-safe data is a confined universe. Nowhere in Plaintiff's Motion, nor in its Complaint, does it challenge the adequacy of CDC's search. Therefore, Plaintiff need not respond to this portion of Defendants' Motion. Dkt. 29 at 10–14.

II. DEFENDANTS IMPROPERLY WITHHELD THE FREE-TEXT RESPONSES.

A. PII is Not at Issue.

Defendants devote close to eleven pages of their brief to uncontested matters. *Id.* at 10–22. Defendants first spend numerous pages arguing that personal identifiable information ("**PII**") such as dates of birth, addresses, social security numbers, etc. within the free-text fields should not be disclosed to Plaintiff because that information is personal information to which Exemption 6,

5 U.S.C. § 552(b)(6), applies. Defendants then go on to argue that the v-safe users have a substantial interest in keeping this information private and that the interests of the public do not outweigh these individuals' interest in keeping this personal information private.

Plaintiff does not contest that this type of information is indeed personal information that should be redacted from the data produced. Indeed, Plaintiff stated as much in the Complaint: "For the avoidance of doubt, Plaintiff is not seeking data from any fields wherein v-safe users were prompted to enter their name, phone number, email address, or any other PII, in order to register for v-safe." Dkt. 1 ¶75 n. 43. It also made this clear in its Motion that "Plaintiff certainly understands that the free-text fields will need to be reviewed for PII." Dkt. 9 at 28.

Further, CDC's v-safe protocol itself states "it is anticipated that v-safe data will be shared with the scientific community," but "[n]o PII [personally identifiable information] will be included in any v-safe analyses, manuscripts, or data sets shared through external data requests." Dkt. 9 at 23 (quoting https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-V6-508.pdf at 13, 15). As CDC implicitly concedes through its own protocol, there is a strong public interest in the de-identified free-text fields.

B. Plaintiff Has Demonstrated a Strong Public Interest in the Free-Text Data and that the Non-Exempt Portions of the Data Are Reasonably Segregable.

Given the above, the crux of the issue before the Court is simply whether FOIA compels CDC to segregate and redact PII from the v-safe free-text fields and then produce the de-identified data. On that issue, the parties fundamentally disagree. Plaintiff has demonstrated that there is a strong public interest in disclosure of the redacted v-safe free text data and that compelling CDC to redact and disclose the data is reasonable, entirely within CDC's capacity, and required by FOIA.

1. Plaintiff has demonstrated strong public interest in the free-text data.

FOIA makes plain that "[a]ny reasonably segregable portion of a record **shall be** provided to any person requesting such record after deletion of the portions which are exempt under this subsection." 5 U.S.C. § 552(b) (emphasis added).

Defendants initially contend that the non-exempt portions are not reasonably segregable in light of Roger Andoh's Declaration which states that review of the 7.8 million entries would take a single FOIA analyst decades. *See* Dkt. 30, Andoh Declaration, ¶ 26. In support, Defendants primarily rely on *Ayuda, Inc. v. Federal Trade Commission*, 70 F. Supp. 3d 247 (D.D.C. 2014), wherein several organizations sought records from a Federal Trade Commission ("**FTC**") database containing consumer complaints about alleged illegal business activity. The *Ayuda* Court ruled that the FTC appropriately applied Exemption 6—including to free-form data fields that contained personal information—for a multitude of reasons; among those reasons was the fact that the plaintiffs' proposed benefits of obtaining the data—to create something akin to Yelp.com reviews—did not shed any light on the FTC's performance but "only serve[d] purely private interests disassociated from monitoring the agency's functioning." *Id.* at 268–69. And while the plaintiffs additionally suggested that the requested information would allow them to discern the effectiveness of FTC's consumer protection efforts by comparing its enforcement initiatives with the volume and nature of the complaints, the court noted that the plaintiffs did not require the free-text fields to do this. Finally, while the court determined that the records were not reasonably segregable in light of the volume of material, it is important to note that the court's decision was based on the fact that the requestors did not contest the level of manual verses automated review required, the amount of hours or the amount of labor required to perform the redactions, or whether the labor and time constituted an undue burden. *Id.* at 275. Such is not the case here.

There are a number of factors that significantly differentiate *Ayuda*. As an initial matter, the most recent version of the v-safe protocol was modified so that it ***explicitly*** calls for CDC to review, redact, and release this "individual-level" data. The October 21, 2022 protocol states:

> A data set with **deidentified individual-level data** will be created and posted twice a year to data.cdc.gov **or through Freedom of Information Act (FOIA) requests**. Data shared externally will go through a **systematic process to remove PII** and be cleared through the relevant clearance processes.[1]

Dkt. 1 ¶ 55 (quoting https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-V6-508.pdf at 12) (emphases added). To date, Defendants have released only portions of the data that they have selected, drawing a hard line at the information Plaintiff seeks.

Additionally, it bears repeating that the data Plaintiff requests pertains to a program that American taxpayers funded—a program that was designed to monitor reactions to vaccines developed and paid for with taxpayer funds. After funding their development and purchase by the U.S. government, American taxpayers then were mandated to inject these products into their bodies—in many cases, under threat of the loss of their livelihoods and inclusion in civil society. Moreover, taxpayers footed the bill when it came to the federal government's actions in enforcing its COVID-19 vaccine mandates as well as its extensive and ongoing efforts to defend its mandates from legal challenges. The American public also funded CDC and all of its efforts to surveil the safety of these novel vaccines. In this case, Plaintiff seeks the requested data to create a more complete picture about the inner workings of the government during this time; the data will reveal what the government knew from citizens participating in its vaccine campaign and when it knew it. While CDC notes that it released partial v-safe data to the public, that data was in response to the controlled and limited check-the-box fields created by CDC in v-safe. Releasing the detailed

[1] https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-V6-508.pdf at 12 (emphases added).

data here is critical because it will allow those severely injured by these products to obtain a reliable and systematic dataset that may scientifically validate their harms so that the medical community will acknowledge them and then provide medical care.

These facts alone are sufficient to wholly distinguish *Ayuda*, which involved a set of data that the requestors hoped to turn into something akin to Yelp.com—a far cry from attempting to understand whether the government's response to millions of vaccine recipients was adequate. The data in *Ayuda* concerned complaints about private companies and their actions, whereas the data sought here concerns a product developed, funded, authorized and approved, promoted, mandated, and surveilled by the federal government and then taken by hundreds of millions of Americans who relied on those government actions. But beyond the obvious difference in the nature of the information being requested, as well as how it relates to a majority of the American public, Plaintiff has demonstrated a clear nexus between obtaining the free-text field data and the ability of the public to gain an understanding about the federal government's—and in particular CDC's—actions and operations during the most significant public health event in recent history.

Notably, as Plaintiff has referenced, a significant number of issues have arisen regarding the v-safe data due to the public's lack of access to it. For example, there have been at least 40 studies published and presentations given—at least 36 by CDC—that involved reviewing and reporting on the v-safe data by the very limited number of researchers who were granted access to it. Unfortunately, all these studies are deeply problematic because—of those that cared to specify how many days of data were reviewed—all but one reviewed no more than 7 days of post-injection health impact data.[2] (The one exception looked at data from days 1-7 and then at day 14). This is,

[2] Anne M. Hause, *Safety Monitoring of COVID-19 Vaccine Among Children and Young Adults in V-safe Advisory Committee on Immunization Practices January 5, 2021*, ACIP (Jan. 5, 2021), https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-01-05/03-COVID-Hause-50

8.pdf (referencing data from days 0-7 after vaccine); Tom Shimabukuro, *COVID-19 Vaccine Safety Update Advisory Committee on Immunization Practices (ACIP)*, ACIP (Jan. 27, 2021), https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-01/06-COVID-Shimabukuro.pdf (presentation by CDC's COVID-19 Vaccine Task Force member presenting v-safe data from days 0-7 after the vaccine); Julianne Gee et al., *First Month of COVID-19 Vaccine Safety Monitoring - United States, December 14, 2020-January 13, 2021*, 70(8) MMWR 283, 287 (Feb. 26, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7008e3-H.pdf (referencing data from days 0-7 after vaccine); Tom Shimabukuro, *COVID-19 vaccine safety update: Advisory Committee on Immunization Practices (ACIP)*, ACIP (Mar. 1, 2021), https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-02/28-03-01/05-covid-Shimabukuro.pdf (same); Johanna Chapin-Bardales, *Reactogenicity Following Receipt of mRNA-Based COVID-19 Vaccines*, 325(21) JAMA 2201 (Apr. 5, 2021), https://jamanetwork.com/journals/jama/fullarticle/2778441 (same); David K. Shay et al., *Safety Monitoring of the Janssen (Johnson & Johnson) COVID-19 Vaccine - United States, March-April 2021*, 70(18) MMWR 680, 683 (May 7, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7018-h.pdf (same); Tom T. Shimabukuro et al., *Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons*, 384(24) N. Engl. J. Med. 2273 (June 17, 2021), https://pubmed.ncbi.nlm.nih.gov/33882218/ (reviewing data from just one day after vaccination); Tom Shimabukuro, *COVID-19 Vaccine safety updates: Advisory Committee on Immunization Practices (ACIP)*, ACIP (June 23, 2021), https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-06/03-COVID-Shimabukuro-508.pdf (referencing data from days 0-7 after vaccine); Julia W. Gargano et al., *Use of mRNA COVID-19 Vaccine After Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory Committee on Immunization Practices — United States, June 2021*, 70(27) MMWR 977 (July 9, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/mm7027e2.htm (referencing v-safe but not interpreting v-safe adverse event data); Sarah Stuckelberger et al., *Current Data on COVID-19 mRNA-Vaccine Safety during Pregnancy Might Be Subject to Selection Bias. Reply to Stroobandt, S.; Stroobandt, R. Data of the COVID-19 mRNA-Vaccine V-Safe Surveillance System and Pregnancy Registry Reveals Poor Embryonic and Second Trimester Fetal Survival Rate. Comment on "Stuckelberger et al. SARS-CoV-2 Vaccine Willingness among Pregnant and Breastfeeding Women during the First Pandemic Wave: A Cross-Sectional Study in Switzerland. Viruses 2021, 13, 1199"*, 13(8) Viruses 1546 (Aug. 5, 2021), https://www.mdpi.com/1999-4915/13/8/1546 (referencing but not interpreting v-safe data); Serge Stroobandt & Roland Stroobandt, *Data of the COVID-19 mRNA-Vaccine V-Safe Surveillance System and Pregnancy Registry Reveals Poor Embryonic and Second Trimester Fetal Survival Rate. Comment on Stuckelberger et al. SARS-CoV-2 Vaccine Willingness among Pregnant and Breastfeeding Women during the First Pandemic Wave: A Cross-Sectional Study in Switzerland. Viruses 2021, 13, 1199*, 13(8) Viruses 1545 (Aug. 5, 2021), https://pubmed.ncbi.nlm.nih.gov/34452410/ (commenting on a study and referencing v-safe); Anne M. Hause et al., *COVID-19 Vaccine Safety in Adolescents Aged 12-17 Years - United States, December 14, 2020-July 16, 2021*, 70(31) MMWR 1053 (Aug. 6, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e1.htm?s_cid=mm7031e1_w (referencing data from days 0-7 after vaccine); Lauren H. Zauche et al., *Receipt of mRNA COVID-19 Vaccines Preconception and During Pregnancy and Risk of Self-reported Spontaneous Abortions, CDC V-safe COVID-19 Vaccine Pregnancy Registry 2020–21*, Res. Sq. (Aug. 9, 2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8366802/ (preprint reviewing v-safe's separate pregnancy registry

data); Christine K. Olson, *COVID-19 Vaccine Safety in Pregnancy: Updates From the V-Safe COVID-19 Vaccine Pregnancy Registry*, ACIP (Sept. 22, 2021), https://stacks.cdc.gov/view/cdc/110034 (discussing v-safe separate pregnancy registry); Anne M. Hause et al., *Safety Monitoring of an Additional Dose of COVID-19 Vaccine - United States, August 12-September 19, 2021*, 70(39) MMWR 1379, 1381 (Oct. 1, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7039-H.pdf (reviewing data from days 0-7 after vaccine); Anne M. Hause, *Early Safety Monitoring For Additional COVID-19 Vaccine Doses: Reports to VAERS and V-Safe Advisory Committee on Immunization Practices October 21, 2021*, ACIP (Oct. 21, 2021), https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/05-COVID-Hause-508.pdf (referencing data from days 0-7 after vaccine); Lauren H. Zauche et al., *CDC v-safe COVID-19 Pregnancy Registry Team. Receipt of mRNA COVID-19 Vaccines and Risk of Spontaneous Abortion*, 385(16) N. Engl. J. Med. 1533 (Oct. 14, 2021), https://www.nejm.org/doi/10.1056/NEJMc2113891?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed (reviewing v-safe data from day 1 after vaccination as well as pregnancy data from a separate pregnancy registry); Pedro L. Moro, *Monitoring the Safety of COVID-19 Vaccines in Pregnancy in the US*, 17(12) Hum. Vaccines & Immunotherapeutics 4705 (Nov. 10, 2021), https://www.tandfonline.com/doi/full/10.1080/21645515.2021.1984132 (referencing v-safe but not interpreting v-safe data); Johanna Chapin-Bardales et al., *Reactogenicity Within 2 Weeks After mRNA COVID-19 Vaccines: Findings From the CDC V-Safe Surveillance System*, 39(48) Vaccine 7066 (Nov. 26, 2021), https://pubmed.ncbi.nlm.nih.gov/34763946/ (reviewing data from days 0-7 and day 14 after vaccine); Anne M. Hause et al., *COVID-19 Vaccine Safety in Children Ages 5-11 years - United States, November 3-December 19, 2021*, 70(5152) MMWR 1755 (Dec. 31, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/mm705152a1.htm?s_cid=mm705152a1_w (referencing data from days 0-7 after vaccine); Lisa R. Lynch et al., *Primer of COVID-19 Vaccines for the Perioperative Physician*, 34(1) J. Neurosurgical Anesthesiology 101 (Jan. 2022), https://journals.lww.com/jnsa/abstract/2022/01000/primer_of_covid_19_vaccines_for_the_perioperative.38.aspx (referencing v-safe but not interpreting v-safe adverse event data); Anne M. Hause et al., *Safety Monitoring of COVID-19 Vaccine Booster Doses Among Adults - United States, September 22, 2021-February 6, 2022*, 71(7) MMWR 249 (Feb. 18, 2022), https://www.cdc.gov/mmwr/volumes/71/wr/mm7107e1.htm?s_cid=mm7107e1_w (referencing data from days 0-7 after vaccine); Anne M. Hause et al., *Safety Monitoring of COVID-19 Vaccine Booster Doses Among Persons Aged 12–17 Years — United States, December 9, 2021–February 20, 2022*, 71(9) MMWR 347 (Mar. 4, 2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8893335/ (same); Luke S. Borthun et al., *Readability of COVID-19 Vaccine Information for the General Public*, 40(25) Vaccine 3466 (May 31, 2022), https://www.sciencedirect.com/science/article/pii/S0264410X22005461?via%3Dihub (referencing v-safe but not interpreting v-safe adverse event data); Nicola Klein & Tom Shimabukuro, *Safety Update of 1st Booster mRNA COVID-19 Vaccination Advisory Committee On Immunization Practices (ACIP) April 20, 2022*, ACIP (Apr. 20, 2022), https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-04-20/03-COVID-Klein-Shimabukuro-508.pdf (referencing data from days 0-7 after vaccine); Tom Shimabukuro, *COVID-19 Vaccine Safety Updates: Primary Series in Children Ages 5–11 Years Advisory Committee on Immunization Practices (ACIP) May 19, 2022*, ACIP (May 19, 2022), https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-05-19/03-COVID-Shimabukuro-508.pdf (referencing data from days 0-7 after vaccine); Hannah G. Rosenblum, *Safety of*

mRNA Vaccines Administered During the Initial 6 Months of the US COVID-19 Vaccination Programme: An Observational Study of Reports to the Vaccine Adverse Event Reporting System and V-Safe, 22(6) Lancet Infect. Dis. 802 (June 2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8901181/ (referencing data from days 0-7 after vaccine); Anne M. Hause et al., *Reactogenicity of Simultaneous COVID-19 mRNA Booster and Influenza Vaccination in the US*, 5(7) JAMA Netw. Open e2222241 (July 2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9287747/ (reviewing data from days 0-7 after vaccine); Anne M. Hause, *Reactogenicity of Simultaneous COVID-19 mRNA Booster and Influenza Vaccination in the US*, 5(7) JAMA Network Open e2222241 (July 5, 2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9287747/ (same); Anne M. Hause et al., *Safety of COVID-19 Vaccination in United States Children Ages 5 to 11 Years*, 150(2) Pediatrics e2022057313 (July 14, 2022), https://publications.aap.org/pediatrics/article/150/2/e2022057313/188023/Safety-of-COVID-19-Vaccination-in-United-States?autologincheck=redirected (same); Anne M. Hause et al., *Safety Monitoring of COVID-19 mRNA Vaccine First Booster Doses Among Persons Aged =12 Years with Presumed Immunocompromise Status — United States, January 12, 2022–March 28, 2022*, 71(28) MMWR 899 (July 15, 2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9290389/ (same); Anne M. Hause et al., *Safety Monitoring of COVID-19 mRNA Vaccine Second Booster Doses Among Adults Aged =50 Years — United States, March 29, 2022–July 10, 2022*, 71(30) MMWR 971 (July 29, 2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9345177/ (same); Anne M. Hause et al., *Safety Monitoring of Pfizer-BioNTech COVID-19 Vaccine Booster Doses Among Children Aged 5–11 Years — United States, May 17–July 31, 2022*, 71(33) MMWR 1047 (Aug. 19, 2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9400528/ (same); Karen K. Wong et al., *Menstrual Irregularities and Vaginal Bleeding After COVID-19 Vaccination Reported to V-Safe Active Surveillance, USA in December, 2020–January, 2022: An Observational Cohort Study*, 4(9) Lancet Digital Health e667 (Sept. 2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9363036/ (not specifying the days of data reviewed); Tom Shimabukuro, *COVID-19 Vaccine Safety Update: Primary Series in Young Children and Booster Doses in Older Children and Adults*, ACIP (Sept. 1, 2022), https://stacks.cdc.gov/view/cdc/120824 (referencing data from days 0-7 after vaccine); Anne M. Hause et al., *Safety Monitoring of Bivalent COVID-19 mRNA Vaccine Booster Doses Among Persons Aged =12 Years — United States, August 31–October 23, 2022*, 71(44) MMWR 1401 (Nov. 4, 2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9639436/ (same); Lindsay K. Tompkins et al., *Association Between History of SARS-CoV-2 Infection and Severe Systemic Adverse Events After mRNA COVID-19 Vaccination Among U.S. Adults*, 40(52) Vaccine 7653 (Dec. 12, 2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9622386/ (same); Anne M. Hause et al., *Safety Monitoring of Bivalent COVID-19 mRNA Vaccine Booster Doses Among Children Aged 5–11 Years — United States, October 12–January 1, 2023*, 72(2) MMWR 39 (Jan. 13, 2023), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9869731/ (same); Tanya R. Myers et al., *The V-Safe After Vaccination Health Checker: Active Vaccine Safety Monitoring During CDC's COVID-19 Pandemic Response*, 41(7) Vaccine 1310 (Feb. 10, 2023), https://www.sciencedirect.com/science/article/pii/S0264410X22015456?via%3Dihub (referencing v-safe but not interpreting v-safe adverse event data); Tom Shimabukuro, *Update on Myocarditis Following mRNA COVID-19 Vaccination Advisory Committee on Immunization Practices (ACIP) June 23, 2022*, ACIP (June 23, 2022), https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-

at best, highly misleading because CDC is fully aware that injuries from COVID-19 vaccines can and do occur well after the first week of vaccination.[3] By way of just one illuminating example, a CDC study published on March 7, 2022 in Lancet looked at 7.8 million v-safe participants and determined that just 0.8%-1.1% of users reported needing medical care.[4] Contrast this to the 7.7% of v-safe users who reported needing medical care when the raw v-safe data was disclosed by CDC as a result of another litigation.[5] This large discrepancy between what the researchers claimed and what the raw data showed was due to the fact that the researchers arbitrarily chose to include only cherry-picked data reported within 7 days of vaccination. Crucially, however, this discrepancy, and the more complete picture that resulted, could only have been discovered by the release—prompted by litigation—of the raw check-the-box data that began to shed light on the government's activities during COVID-19.

It is, therefore, reasonable to anticipate that even more of the same will occur with the additional release of the free-text data here. Access to the free-text data will allow scientists, medical professionals, and the public at large to fully check the work, so to speak, of the public servants who reviewed this data and published studies on it. As the court in *Judicial Watch v.*

2022-06-22-23/03-covid-shimabukuro-508.pdf (referencing v-safe but not interpreting v-safe adverse event data).

[3] For example, myocarditis can arise at least 42 days after vaccination, *see* https://pubmed.ncbi.nlm.nih.gov/34614329 at Figure 1. Thrombosis with thrombocytopenia syndrome (TTS), which can also be caused by the COVID-19 vaccine, can arise up to 18 days after vaccination. *See* https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-12-16/02-COVID-See-508.pdf at slide 16.

[4] Hannah G. Rosenblum et al., *Safety of mRNA Vaccines Administered During the Initial 6 Months of the US COVID-19 Vaccination Programme: An Observational Study of Reports to the Vaccine Adverse Event Reporting System and V-Safe*, 22(6) Lancet 802 (Mar. 7, 2022), https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(22)00054-8/fulltext#seccestitle130.

[5] https://icandecide.org/v-safe-data/; https://data.cdc.gov/Public-Health-Surveillance/v-safe-COVID-19/dqgu-gg5d.

Rossotti noted, the question is not whether a plaintiff can prove it will catch the government in a mistake; similarly, this case is not about whether the COVID-19 vaccine is safe. Instead, the question is "whether disclosure of the requested documents is likely to contribute to public understanding of [the government's COVID-19 operations]—a goal that disclosure will promote regardless of what the documents reveal." *Judicial Watch v. Rossotti*, 326 F.3d 1309, 1314 (D.C. Cir. 2003). Contrary to Defendants' contentions, "the American people have as much interest in knowing that [the government upheld its regulatory duties] as they have in discovering that they [did] not." *Id.*; *Lurie v. Department of the Army*, 970 F. Supp. 19, 35 (D.D.C. 1997) ("As with FOIA generally, the fundamental question in evaluating the public interest [under Exemption 6] is whether disclosure would provide a view of the agency's activities, thereby revealing what our government is up to." (internal quotation marks omitted)). Thus, while the check-the-box data was, belatedly, helpful in shedding some light on the government's actions during the pandemic, it does not come close to telling the complete picture. In light of the above, there is good reason to think the requested free-text data will shed new and clarifying light on the CDC studies.

Importantly, this need for the free-text field data was created by CDC itself; CDC specifically made the choice not to use the check-the-box fields to ask users if they experienced any of the 15 adverse events of special interest ("**AESI**") that CDC itself identified in the very first version of its v-safe protocol from November 19, 2020. Dkt. 1 ¶ 48; Dkt. 1-7 at 42. This list included acute myocardial infarction, anaphylaxis, Guillain-Barré myocarditis/pericarditis, stroke, and other harms we now know are associated with COVID-19 vaccines. Consequently, the only place v-safe users could report these anticipated AESIs, and anything else they felt important enough to convey to their government, was the free-text fields, which is why full access to this

data is so vital.[6] Thus, unlike in *Ayuda*, Plaintiff has explained why the information in the free-text fields specifically (and not just the information in the check-the-box fields) is required to achieve both the Freedom Coalition's goal and the goal of FOIA. "FOIA was [] enacted to 'pierce the veil of administrative secrecy and to open agency action to the light of public scrutiny.'" *Batton v. Evers*, 598 F.3d 169, 175 (5th Cir. 2010) (quoting *Dep't of the Air Force v. Rose*, 425 U.S. 352, 361 (1976)). That light is needed here, and Plaintiff has demonstrated a strong public interest in the information it seeks.

2. *The non-exempt portions of the data are reasonably segregable.*

At the same time, the data at issue in this case would not be difficult to obtain. While Defendants contend segregation is not possible, Defendants' own Motion proves they do have the ability to search for and locate PII—and in doing so have demonstrated that the data is indeed reasonably segregable. This rebuts any presumption that the agency may have complied with its obligation as it is "sufficient evidence" to the contrary. Dkt. 29 at 3. Defendants established they are in fact able to do precisely what is required by FOIA and reviewed a "random sample of 500 Free-Text Responses" that purportedly contained "dozens of responses" with PII. Dkt. 29 at 26. Defendants were then able to perform a "similar random search of 500,000 Free-Text Responses" which again purportedly found additional PII (although CDC did not disclose the percentage of those responses that contained PII). Dkt. 29 at 26.

[6] To the extent Defendants contend the MedDRA codes are sufficient, they are not. CDC engaged a third-party contractor to review each and every free-text field (something they are saying now would take decades) and to "translate" what each v-safe user wrote into MedDRA codes (standardized medical terminology). In assessing whether these codes are sufficient, the Court may consider the significant differences between what the researchers who reviewed only 8 days of data concluded and what the universe of raw data actually indicated. *See* supra at 10. In other words, "just trust us" is no longer sufficient.

Crucially, it is not clear—as Defendants do not explain—how Defendants selected these "random" samples. Plaintiff is unable to confirm whether or not the samples were random and so cannot concede that the amount of purported PII is representative of the universe of data. If these search results are to be relied on by the Court, Plaintiff requests that the search results be submitted *in camera* to the Court for confirmatory review (or, alternatively, filed on the docket with appropriate redactions). Further, Plaintiff would request specific details about these searches such as the amount of time they took and whether they factored into Andoh's calculations regarding his estimations on a CDC analyst's speed of review, as well as how the CDC randomized and selected the entries that were reviewed and the percentage of the 500,000 entries that contained PII.

But even assuming, *arguendo*, that Defendants' representations regarding these searches are accurate and the samples were correctly randomized, there are nonetheless a multitude of reasons why Defendants' "Chicken Little" analysis is incorrect. First of all, while the free-text fields are limited to 250 characters, the 14,703 free-text entries CDC has produced from its v-safe motivation survey data show that the average entry was merely 35 characters. Dkt. 1 ¶ 80.[7] Defendants do not dispute this. Instead, Defendants irrationally contend that a FOIA analyst is able to review only 2,525 responses per week, which would equal 88,375 characters (at an average length of 35 characters each).

[7] Andoh's Declaration indicates that CDC inadvertently permitted two free-text fields to accept up to 4,000 characters for prompts on "Any other symptoms or health conditions you want to report" and on the type of healthcare received. Dkt. 30 ¶ 17. CDC's mistake—which may have resulted in more data—should not cut against Plaintiff. If anything, the fact that some individuals may have felt the need to take up more than 250 characters in response to these particular questions regarding their health after receipt of the vaccine is indicative that there may be issues about which the public should be aware. In any event, CDC does not say how many entries had the 4,000 character limit and what was the average character length of these entries.

Consider that a typical page contains an average of approximately 3276 characters per page. [8] Therefore, 2,525 responses equals around 88,375 characters, or approximately 27 pages. That means—based on Defendants' own Andoh Declaration—the hypothetical analyst will review *only* **27 pages in a 40-hour week** (or 0.67 pages per hour). Dkt. 30 at 13. This is facially unreasonable and demonstrates that Andoh's declaration was built upon unsupportable tenets fabricated to justify the indefensible position that Defendants have taken for almost a year in order to keep these records from the public. Further proof of Defendants' fig leaf is revealed by the existing evidence showing the free-text fields were already reviewed, one by one, at an exponentially faster rate for more complicated MedDRA coding. *See infra*.

As Plaintiff has observed, there are existing programs that can automate much of this process by flagging and redacting, *inter alia*, names, phone numbers, addresses, email, social security numbers, URLs, IP addresses, age, routing numbers, credit card numbers, bank account numbers, etc. *See* Dkt. 9 at 28 n.42. Defendants have no coherent response (or evidence) to refute this point nor do they explain why CDC is unable to use its discretionary budget to purchase a program that can automate detecting PII if it does not already have one available.[9] Automating this process would **significantly** cut down on the Defendants' already inflated estimations regarding both the labor and the amount of hours required to review and redact this data such that production would not be unreasonably burdensome.

[8] The 3,276 average characters per page assumes 12 point font, Times New Roman, single spaced, and 1 inch margins.

[9] Andoh's Declaration baselessly states that "detection services were created to look for very specific information, which would not be applicable to all types of PII, especially in a narrative format." Dkt. 30 ¶ 38. This is simply not true. In the age of artificial intelligence, this type of redaction is easily automated.

Additional key evidence proves that Defendants' calculations of years or even decades being needed to review the entries is hyperbolic: most of the MedDRA coding review has already taken place. Although Defendants make much of the fact that they are purportedly unable to modify CDC's existing MedDRA contract to have the free-text fields reviewed for PII in addition to the review for conversion into MedDRA coding, it is worth noting that CDC easily could have, and should have, drafted this contract to incorporate PII review from the outset. All it needed to do was follow its own v-safe protocol, which even in the earliest November 19, 2020 version called for the release of this data.[10] Equally telling, Defendants have put forward no evidence that the vendor would not agree to such a modification so that Defendants could comply with the law (for a reasonable charge).

This is especially so given that CDC was fully aware that the public desired this data long before entering into the MedDRA contract. In fact, CDC was actually engaged in litigation about the release of this specific data for well over a year prior to the September 26, 2022 MedDRA code contract, and thus had plenty of time to modify the contract to incorporate PII review.[11] The fact that CDC chose not to do so, and now compliance with FOIA will require an additional PII review of the same data, is a situation entirely of CDC's own making. CDC's purposeful failings cannot be held against the Plaintiff.

Additionally, the MedDRA contract—and its resulting completed review and conversion of more than 6.8 million records—is actual proof that the review can be done and in **significantly**

[10] https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-V5-508.pdf at 12.

[11] *Compare* https://icandecide.org/wp-content/uploads/2021/12/001-COMPLAINT-24.pdf (noting FOIA requests for v-safe data were submitted June 24, 2021, and suit was filed December 28, 2021), *with* Dkt. 1-1 at 2 (listing September 26, 2022, as the date of the MedDRA code contract); *see also* https://www.usaspending.gov/award/CONT_AWD_75D30122F15339_7523_GS35F080CA_4732 (MedDRA contract).

less time than CDC claims. This is fatal to Defendants' cries that the task is near impossible. CDC's MedDRA contract is dated September 26, 2022, which is presumably, then, the earliest possible date that work began.[12] CDC produced the MedDRA codes for 6.8 million free-text fields by June 1, 2023 in a separate litigation.[13] This equated to approximately 837,000 free-text responses reviewed and coded per month; potentially a higher rate if the start date was later than September 26, 2022. Of note, by Defendants' own admission, the review of this data for MedDRA coding was much more complex than is required here.

> MedDRA coding facilitates research by **converting highly variable language describing things such as a patient's description of symptoms into consistent, universally accepted, and easily ascertainable medical technology**, and converting the Free-Text Responses to MedDRA codes ensures the information can be disclosed to both researchers and the public without inadvertently releasing personal identifying information.

Dkt. 29 at 38.

Thus, the MedDRA review demanded that reviewers carefully read every word of every one of the millions of free-text field entries, consider which of the thousands upon thousands of existing MedDRA code(s) applied, and then document those codes. And yet, Defendants were able to process at least 837,000 of these fields per month. Defendants do not, because they cannot, explain how it was able to review and produce 6.8 million responses by June 1, 2023 in the form of MedDRA codes (a more complex process than just reviewing for PII) while a similar review and redaction process to just remove PII would differ so greatly that it is not possible—or that it would take 59 years. Brehm Decl., App. 01, ¶ 5. Applying that same rate to the 7,800,000 free-

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[12] https://www.sirillp.com/wp-content/uploads/2023/12/Vsafe-MedDRA-Contract-f04667c7e74ea3567e199b14c086f481.pdf.

[13] *Informed Consent Action Network v. CDC*, 1:21-cv-01179-RP (W.D. Tex. Dec. 12, 2021) (Complaint); *see also* Declaration of Elizabeth A. Brehm ("**Brehm Decl.**"), App. 01, ¶¶ 4–5.

text fields at issue here, Defendants are able to review and produce the data in no more than 9.3 months. Thus, Plaintiff requests the Court require Defendants to produce the requested data, on a rolling basis, within no more than 9.3 months of the Court's order. And given the delay tactics of Defendants to date, and the fact that this data was requested almost a year ago, a more aggressive schedule is warranted. As the Court is aware, it "may use its equitable powers to require an agency to process documents according to a court-imposed timeline." *Clemente v. FBI*, 71 F. Supp. 3d 262, 269 (D.D.C. 2014).

A helpful comparator can be seen in another recent FOIA matter from this District where the plaintiff sought close to 5 million pages of records. While recognizing "the limited resources" that a federal agency has dedicated to FOIA requests, the court held that "**the number of resources an agency dedicates to [FOIA] requests does not dictate the bounds of an individual's FOIA rights**." *PHMPT v. FDA*, No. 4:22-cv-00915-P, 2023 WL 3335071, at *2 (N.D. Tex. May 9, 2023) (emphasis added). This is especially so where the reason the data will take additional time to review is entirely the fault of agency (the case here because CDC did not call for data deidentification during the MedDRA review process or begin processing Plaintiff's request sooner). Notably, the FDA steadfastly claimed in *PHMPT*, like CDC here, that production of the requested documents was wholly unfeasible and that it could not produce more than 500 pages per month. *See PHMPT*, Dkt. 29 at 2-3, 14 (N.D. Tex. Dec. 13, 2021) (FDA brief claiming the plaintiff's request, or anything beyond producing 500 pages per month, was "simply not possible for FDA to meet" and "well outside the realm of reason"). Yet, when the court ordered the documents to be produced at a rate of at least 55,000 pages per month, FDA was in fact able to "marshal every possible resource available to it," including hiring contractors and reassigning staff, to produce the documents at a rate exceeding 55,000 pages per month. *PHMPT*, Dkt. 37 at

1–2 (N.D. Tex. Dec. 13, 2021). Here, there is need for even less speculation regarding the agency's capacity because CDC has already demonstrated it is able to process these precise free-text fields at a rate of at least 837,000 fields per month.

And if all that were not enough, there is yet additional support for the fact that the free-text fields are reasonably segregable: CDC's existing contract for reviewing, redacting, and providing similar VAERS data to the public. Although Defendants made sure to emphasize that the contract to redact PII from VAERS entries is separate and does not cover v-safe, Defendants fail to explain why they cannot implement a similar contract for redacting PII from its equally as important brand-new vaccine safety data monitoring system designed to "enhance VAERS." Dkt. 30 ¶ 37. The only other argument offered was that such a process would take years (which is refuted above). Dkt. 29 at 39. The fact remains that redacting PII from these types of entries is possible but, unfortunately, CDC has demonstrated repeatedly that it has no intention of taking, *or even beginning to take*, the necessary steps to release this data unless obligated by law or court order—despite the fact that its own v-safe protocol called for de-identification and disclosure of the record level data.

Finally, with respect to Defendants' concern regarding the ability to connect unspecified pieces of information to identify individual users even after the redactions process, *Ayuda* points out that just because a requestor receives many pieces of information that "might theoretically enable the accused to identify [an individual]" does not mean a requestor is not entitled to it. 70 F. Supp. 3d at 271. To succeed on such an argument, the government must provide some evidence suggesting that disclosure will actually or potentially affect the likelihood an individual will be identified. *Id.* Defendants have not even made an attempt to do that here.

III. PLAINTIFF ALSO PREVAILS ON THE REMAINING CLAIMS.

A. Defendants Did Not Timely Respond to Plaintiff's Appeal.

While Defendants claim that they responded to Plaintiff's administrative appeals, they gloss over the fact that their responses were late and, accordingly, violated FOIA. Once again, pursuant to 5 U.S.C. § 552(a)(6)(A)(ii) and 5 U.S.C. § 552(a)(6)(B)(i), Defendants had 30 business days from January 17, 2023—March 2, 2023—to respond to Plaintiff's appeal of the denial of its request for expedited processing and a fee waiver. Dkt. 1 ¶¶ 60–67. Defendants failed to do so in a timely manner.

Further, on March 31, 2023, Plaintiff submitted an appeal of the fee waiver denial. Dkt. 1 ¶ 65. HHS acknowledged the appeal on April 1, 2023, but failed to otherwise respond within the maximum 30 days set forth by FOIA. Dkt. 1 ¶ 65. *See* 5 U.S.C. § 552. In fact, only on July 5, 2023, several weeks after Plaintiff was forced to file suit, did Defendants issue a response administratively closing the appeal due to the instant litigation.

B. A Fee Waiver is Appropriate Under the Statute.

Contrary to Defendants' contention, Plaintiff has demonstrated entitlement to a fee waiver pursuant to 5 U.S.C. § 552(a)(4)(A). Under FOIA, fees must be waived where "disclosure of the [requested] information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester." 5 U.S.C. § 552(a)(4)(A)(iii). Additionally, "Congress amended FOIA to ensure that it is **liberally construed in favor of waivers** for noncommercial

requesters." *Judicial Watch*, 326 F.3d at 1312 (internal quotation marks omitted) (emphasis added).

Here, the information sought will certainly contribute to the public's understanding of the COVID-19 vaccines because it consists of direct source material. This is particularly significant because, as detailed above, various scientists—including those at CDC—have published over 40 studies and presentations to support the claim that COVID-19 vaccines are safe. The primary information used in these studies is v-safe's health impact data, with a focus on the rate of people who reported needing medical care after the vaccine. Indeed, those studies formed the core of CDC's support for the safety of COVID-19 vaccines. As noted above, though, the studies uniformly report only the *first week* of health impact data after injection (with a single exception).[14] When the check-the-box data was released and compared to these studies' findings, it became apparent that there were significant distortions in the studies' findings, and these necessitate the public's access to the full unfiltered data CDC has in its possession.

Defendants cite *Nat'l Sec. Counselors v. U.S. Dep't of Justice*, arguing that, to be entitled to a fee waiver, requestors must provide specific details on how the information will be disseminated with, for example, specifics on its website traffic. 848 F.3d 467, 474 (D.C. Cir. 2017). Such a requirement is wholly inapplicable here, though, where Plaintiff has repeatedly explained that Freedom Coalition was formed exclusively for the purpose of obtaining and making public the v-safe free-text data. *See, e.g.*, Dkt. 20-1 at 2-3. While Plaintiff's website is open, operational, and currently contains a list of its members,[15] its *current* website traffic is entirely irrelevant to its *anticipated* traffic, assuming it accomplishes its purpose and obtains the free-text data. Put simply,

[14] https://pubmed.ncbi.nlm.nih.gov/34763946/.

[15] https://drsforchoice.org.

when a website's sole purpose is to disclose data not yet obtained, there is no reason for people to visit it. Inevitably, Plaintiff's website traffic would grow exponentially were it to obtain the free-text data.

In the recent analogous case *PHMPT*, the organization Public Health and Medical Professionals for Transparency ("**PHMPT**") sought close to 5 million pages of records in the Comirnaty biological product file. In granting PHMPT the requested documents, the court noted that PHMPT represented that "it exists for the sole purpose of disseminating to the public the data and information in the biological product files for each of the COVID-19 Vaccines." *Id.*, 2023 WL 3335071, at *2 (internal quotation marks omitted). Notably, PHMPT was not required to show its website traffic or provide specific details on how it "would disseminate the requested records to a reasonably broad audience of persons interested in the subject." Dkt. 29 at 48. Nonetheless, the data has been indeed widely disseminated and reported on as it has been received.[16]

Finally, it is plain that disclosure of the information is not primarily in the commercial interests of Plaintiff. Plaintiff was formed entirely to obtain v-safe data. To that end, Plaintiff does not expect or seek monetary gain as a result of obtaining the data; it will only publicly disseminate the information. Plaintiff is thus entitled to a fee waiver.

CONCLUSION

The CDC utilized taxpayer dollars to collect information from Americans about a product that American taxpayers funded and were, in many situations, mandated to take. This information, regardless of what it reveals, will unquestionably shed light on the federal government's—and in

[16] https://www.reuters.com/legal/government/paramount-importance-judge-orders-fda-hasten-release-pfizer-vaccine-docs-2022-01-07/; https://news.bloomberglaw.com/health-law-and-business/why-a-judge-ordered-fda-to-release-covid-19-vaccine-data-pronto;https://www.medpagetoday.com/special-reports/exclusives/97544;https://windsor.ctvnews.ca/data-is-power-experts-weigh-in-on-court-ordered-release-of-pfizer-vaccine-documents-1.5816089.

particular CDC's—actions and operations during one of the most significant public health events ever. CDC has a clear obligation under FOIA to release the free-text data at issue and, as CDC has demonstrated (namely through its already-conducted review of the same data), reviewing, redacting, and releasing this data in a timely fashion is well within its capacity. Therefore, Defendants have violated FOIA by refusing to release the requested information and Plaintiff asks that this Court grant its Motion for Summary Judgment and deny Defendants' Cross-Motion for Summary Judgment. Plaintiff also asks that the Court require Defendants to produce the requested data, on a rolling basis, with production to be complete within no less than 9.3 months of the Court's order. However, given the exigencies—including the purposeful stonewalling by the agency—and urgency of releasing this data, Plaintiff asks that the Court enter any shorter timeframe that it deems appropriate.

December 8, 2023

Respectfully submitted.

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CERTIFICATE OF SERVICE

On December 8, 2023, I electronically submitted the foregoing document with the clerk of court for the U.S. District Court, Northern District of Texas, using the electronic case filing system of the court. I hereby certify that I have served all parties electronically or by another manner authorized by Federal Rule of Civil Procedure 5(b)(2).

/s/ John C. Sullivan
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